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# Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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# Office Action Summary

Application No.	Applicant(s)	
10/516,741	JESPERSEN ET AL.	
Examiner	Art Unit	
TERESA WESSENDORF	1639	

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The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the o	correspondence a	dress
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING D. A Edensions of time may be available under the provisions of 3 CFR 1.13 after SIX (6) MONTHS from the mailing date of the communication.  If NO period for right is generalled above, the maculum statuture production of the communication of the c	ATE OF THIS COMMUNICATION  (A) In no event, however, may a reply be tirting apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	N. nely filed the mailing date of this of D (35 U.S.C. § 133).	,
Status			
1) Responsive to communication(s) filed on 9/18// 2a) This action is FINAL. 2b) This 3) Since this application is in condition for allowan closed in accordance with the practice under E	action is non-final. ace except for formal matters, pro		e merits is
Disposition of Claims			
4) ☐ Claim(s) 1-3 and 7-15 is/are pending in the app 4a) Of the above claim(s) 3.10.12 and 14 is/are 5) ☐ Claim(s) is/are allowed.  6) ☐ Claim(s) 1-2. 7-13 and 15 is/are rejected.  7) ☐ Claim(s) is/are objected to.  8) ☐ Claim(s) are subject to restriction and/or	withdrawn from consideration.		
Application Papers			
9) The specification is objected to by the Examiner  10) The drawing(s) filed on is/are: a) acce Applicant may not request that any objection to the c Replacement drawing sheet(s) including the correct  11) The oath or declaration is objected to by the Ex	epted or b) objected to by the drawing(s) be held in abeyance. Se on is required if the drawing(s) is ob	e 37 CFR 1.85(a). jected to. See 37 C	
Priority under 35 U.S.C. § 119			
12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of:  1. Certified copies of the priority documents 2. Certified copies of the priority documents 3. Copies of the certified copies of the prior application from the International Bureau * See the attached detailed Office action for a list of	s have been received. s have been received in Applicative documents have been received (PCT Rule 17.2(a)).	ion No ed in this Nationa	Stage
Attachment(s)			
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)	Interview Summary Paper No(s)/Mail D     Netice of Informatic	ate	

Attachment(s)		
Notice of References Cited (PTO-892)	4) Interview Summary (PTO-413)	
Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date	
3) Information Disclosure Statement(s) (PTO/S5/08)	5) Notice of Informal Patent Application	
Paper No(s)/Mail Date	6) Other:	

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#### DETAILED ACTION

#### Status of Claims

Claims 1-3 and 7-15 are pending.

Claims 3, 10 (with respect to the non-elected species), 12 (with respect to the non-elected species) and 14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

Claims 1-2, 7-13 and 15 are under examination.

## Withdrawn Rejection

In view of the amendments to the claims and applicants' arguments the 35 USC 112 first paragraph rejections (written description and new matter) and the 35 USC 103 over Hutchens are withdrawn.

#### Claim Rejections - 35 USC § 112

Newly added claim 15 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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#### New Matter Rejection

Newly added claim 15 is not supported in the as-filed specification. MPEP 714.02 clearly states that applicants point out where in the original specification the new claim limitations find support.

Applicants contend that support for new claim 15 can be found in the specification on page 18, lines 25-30, page 19, lines 23-25 and Figure 3.

In reply, none of the above-cited section supports new claim 15. For example, page 18, lines 25-30 recites (please note that there is no line 30 at page 18. It is presumed that applicants meant paragraph bridging pages 18 and 19):

It should be noted that in the present context, the term "whole-cell configuration" denotes not only configurations in which a whole cell has been brought in contact with the substrate at a measuring site and has been punctured or, by means of a pore-forming substance, has been opened to electrical contact with the cell interior, but also configurations in which an 18 excised cell membrane patch has been arranged so that the outer face of the membrane faces "upwardly", towards a test sample to be applied.

#### Page 19, lines 23-25 recites:

A number of test cells can be studied at any one time and the electrophysiological measurements made and analysed to indicate which if any, of the test cells exhibit phenotypes different to that of the control cells.

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Figure 3, page 13 of the Brief description of the drawings states:

Figure 3 - Schematic diagram of the preferred chip construct. Constructed with: 1. Chip housing. 2. Micro structured unit. 3. Glass/silica membrane on micro structured unit. 4. Cell containing channel/compartment containing extracellular buffer solution and compound. 5. Channel containing intracellular buffer solution and mRNA from cell in whole-cell configuration. 6. Inlet port/pipetting well for introduction of cells and compound. 7. Cell capture site consisting of an orifice in the membrane 3. The orifice is appropriately shaped to enable a gigaseal and whole-cell formation. 8. Cell in suspension. 9. Micropumps.

#### Written Description

The specification fails to provide an adequate written description of a substrate used in the method which comprises a first surface part and an opposite second surface part, wherein the first part has a plurality of sites each of which is adapted to hold an ion channel-containing structure. The specification merely provides the above single statement, as well, as the claims. There is no description in the specification as to the kind/type of first surface part and what would be considered a first part and a second part of the surface and to their positions being opposite.

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In patent applications, Examples normally provide the details of the actual work done by the inventor. It is this Example that provides quidance to one skilled in the art whether applicant is in possession of the claimed invention. However, the Examples do not describe any two-part substrate. Except for the above said single statement, the disclosure is lacking in the description of said two-surface substrates. The law clearly indicates that a patent specification must describe the claimed invention in sufficient detail (not in general terms). An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures and formulas to show that the invention is complete. Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPOM 1961, 1966 (Fed. Cir. 1997); MPEP 2163. The general statements in the specification are therefore not a detail description of the invention. A "written description of an invention involving a chemical genus, like a description of a chemical species, requires a precise definition, such as by structure, formula [or] chemical name of the claimed subject

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matter sufficient to distinguish it from other materials". University of California v. Eli Lilly and Col, 43 USPQ 2d 1398, 1405(1997), quoting Fiefs V. Revel, 25 USPQ 2d 1601m 16106 (Fed. Cir. 1993.

## Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-2 and 7-13 and 15, as amended and added, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reasons of record as repeated below, for only the rejections that are maintained.

#### A. Withdrawn

B. The claimed a "heterologous DNA sequence" is unclear, within the claimed context, as to the scope of the heterologous DNA sequence in the different plurality of cells especially in the absence of positive definition/support in the specification.

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#### Response to Arguments

Applicants have directed the Examiner's attention to page 11, lines 9-14 of the specification which defines the term.

The DNA sequence introduced to the target cell is heterologous DNA, by which we mean a DNA sequence that has been introduced to the ceil over and above the cell's normal DNA contents, and wherein each heterologous DNA member of the DNA library differs from each other member by one or more nucleotides. (reproduced for the Examiner's convenience, emphasis added)

In response, this cited section is unclear as to the phrase "over and above the cell's normal DNA contents". It does not give an amount/concentration (if this is what is intended) for a cell's normal DNA contents especially as applied to the claimed any type and number of cells. The term heterologous goes against the conventional wisdom in the art of two different compounds. That is, a DNA and another different compound e.g., reporter.

C. "The cell of interest" is unclear as to the basis or standard by which one bases the cell of interest especially in the absence of positive support in the specification.

# Response to Arguments

Applicants argue that the cell and/or genetic material of interest are derived from the heterologous DNA, supported in the specification on page 2, lines 13-14.

In response, it is unclear how a cell of interest can be "derived" from a heterologous DNA. Furthermore, it is unclear as to the cell derivation from a heterologous DNA when each cell expresses the heterologous DNA.

D. It is unclear as to the "genetic material" the cell of interest that is being referred to. Is this the mRNA or heterologous DNA? (See Fig. 2 above, which refers only to mRNA and not genetic material). Thus, there is an inconsistency in what is being claimed.

#### Response to Arguments

Applicants argue that the genetic material is derived from the heterologous DNA, supported in the specification on page 2, lines 13-14 as recited above.

In response, please see the reply above.

#### E. Withdrawn

F. In claim 7 "each different heterologous DNA sequence is part of a cDNA library" is confusing as to how the DNA sequence is only a part rather than the cDNA library itself i.e., that the DNA is a cDNA library.

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## Response to Arguments

Applicants argue that the DNA is accurately described as part of the library. Furthermore, a library is comprised of a collection of cDNA sequences (heterologous DNAs) generated from mRNA (messenger RNA) sequences containing vectors, promoters etc. Therefore, Applicants contend that each heterologous DNA sequence is accurately characterized as part of said library.

In reply, is part of the library the promoters, vectors and etc. as stated above? However, the specification does not disclose said promoters or vectors or other compounds as a part of the cDNA library. Thus, applicants' arguments as to the DNA generation from mRNA is not commensurate in scope with the claims, which does not recite said mRNA containing the different components, vectors, promoters etc.

G. Claim 13 "spaced-apart" locations are indefinite as to how or what the spacing of the cells is such that each is apart from each other. This term is a relative term. It is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

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## Response to Arguments

Applicants argue that as shown in Figure 2, a single cell target cell must be positioned in the test site for expression and functional screening. Therefore, for the assay to function the cells must be spaced-apart on the substrate. The Examiner is required to give the "broadest reasonable interpretation" to any claim limitations. Accordingly, the PTO may not disregard the structure disclosed in the specification corresponding to such language when rendering a patentability determination. In the context of the specification and claims, "spaced apart" means that at least two cells are not touching each other.

In reply, it is unclear as to applicant's reference to "single cell target cell" and test site or the structure given in the specification. While the examiner is required to give the broadest reasonable interpretation of the claims however, the interpretation must be consistent with the description in the disclosure. Thus, the claimed "spaced apart" defined as "not touching each other" is unclear as to the distance of not "touching each other". Is it a distance in mu, mm, meter etc and is the "spaced apart" uniform? The specification does not define how close or apart "touching each other" entails.

Newly amended claims 1-2 and 7-13 and 15 are rejected under 35 USC 112,  $2^{\rm nd}$  paragraph as follows:

- 1. It is not clear as to what comprise a "first surface part" and "an opposite second surface part" and how the first part is considered opposite to the second part. It is not clear as to the "extent" or metes and bounds of said "part". Furthermore, it is not clear how the plurality of sites of the first part is "adapted" to hold an ion channel-containing structure. It is further unclear whether the ion-channel containing structure is the heterologous DNA.
- 2. Claim 8 does not further limit the base claim 1 as the limitation recited in claim 8 is already recited in the base claim 1.
- 3. Claim 15 is indefinite as to the "measuring site one at a time" especially since it lacks antecedent basis of support from the base claim 1. Also, the phrase "wherein individual whole cell being tested are spaced apart from cells a waiting testing and cells that have already been tested" is unclear as to the simultaneous presence of said "awaiting testing" and "had been tested". There are no qualifying features that differentiates between (or among) said cells.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### Claim Rejections - 35 USC § 102/103

Claims 1-2, 7-13 and 15, as amended and added, are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Qin (6994993).

Qin discloses at col. 20, line 1 up to col. 22, line 50:

The present invention provides a whole cell or isolated cell membrane method to detect compound modulation of human .beta.1A sodium channel subunit.

The method comprises the steps;

- contacting a compound, and a cell or isolated cell membrane that contains functional human .beta.1A sodium channel subunit, and
- 2) measuring a change in the cell or isolated cell membrane in response to modified human .beta.lA sodium channel subunit function by the compound.

The measurement means... can be defined by comparing a cell or cell membrane that has been exposed to a compound to an identical cell or cell membrane preparation that has not been similarly expose to the compound. Alternatively two cells, one containing functional human .beta.1A sodium channel subunit and a second cell identical to the first, but lacking functional human .beta.1A sodium channel subunit could be both used. Both cells or cell membranes are contacted with the same compound and compared for differences between the two cells.

Particularly preferred cell based assays (or cell membrane assays, if suitable) are those where the cell expresses an endogenous or recombinant sodium .alpha. channel subunit simultaneously with recombinant human .beta.lA. In these assays, a putative modulating compound can be analyzed for

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its effect on electrophysiological changes to the sodium flux upon the cell for altered expression of beta1A expression, or altered expression of the alpha/beta1A complex. Cells expressing recombinant human beta 1A are subjected to electrophysiological analysis to measure the total influx of sodium ions across the cell membrane by way of voltage differential using techniques well known by artisans in the field and described herein, including patch clamp voltage techniques ..... Compounds that affect the proper function of human beta 1 may increase or decrease the capacity to open the Na channel, may increase or decrease the rate of Na influx (thus affect the change of membrane potential), may increase or decrease the rate of desensitization or re-sensitization of the channel. The term "test compound" or "modulating compound" as used herein in connection with a suspected modulator of human betalA refers to an organic molecule that has the potential to disrupt specific ion channel activity or cell surface expression of human beta 1A. For example, but not to limit the scope of the current invention, compounds may include small organic molecules, synthetic or natural amino acid peptides, proteins, or synthetic or natural nucleic acid sequences, or any chemical derivatives of the aforementioned.

The term "cell" refers to at least one cell, but includes a <u>plurality of cells</u> appropriate for the sensitivity of the detection method. Cells suitable for the present invention may be bacterial, yeast, or eukaryotic. For assays to which electrophysiological analysis is conducted, the cells must be eukaryotic, preferably selected from a group consisting of Xenopus oocytes, or PC12, <u>COS-7</u>, <u>CHO</u>, <u>HEK293</u>, SK-N-SH cells.

The term "high throughput" refers to an assay design that allows easy analysis of multiple samples simultaneously, and capacity for robotic manipulation....Examples of assay formats include 96-well or 384-well plates, levitating droplets, and "lab on a chip" microchannel chips used for liquid handling experiments.

The cellular changes suitable for the method of the present invention comprise directly measuring changes in the function or quantity of human.beta.lA sodium channel subunit, or by measuring downstream effects of human

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beta.1A sodium channel subunit function, for example by measuring secondary measenger concentrations or changes in transcription or by changes in protein levels of genes that are transcriptionally influenced by human beta.1A sodium channel subunit, or by measuring phenotypic changes in the cell. Preferred measurement means include changes in the quantity of human beta.1A sodium channel subunit protein, changes in the functional activity of human beta.1A sodium channel subunit. Changes in the levels of mRNA are detected by reverse transcription polymerase chain reaction (RT-PCR) or by differential gene expression.

The present invention is also directed to methods for screening for compounds that modulate the expression of DNA or RNA encoding Human beta.1A sodium channel subunit as well as the function of Human beta.1A sodium channel subunit protein in vivo. Compounds may modulate by increasing or attenuating the expression of DNA or RNA encoding a Human beta.1A sodium channel subunit, or the function of a Human beta.1A sodium channel subunit protein. Compounds that modulate the expression of DNA or RNA encoding a Human beta.1A sodium channel subunit or the function of a Human beta.1A sodium channel subunit protein may be detected by a variety of assays.

Qin discloses at e.g., col. 19, lines 45-65 the two-part

#### substrate:

Other methods for detecting Human .beta.1A sodium channel subunit activity involve the direct measurement of Human .beta.1A sodium channel subunit activity in whole cells transfected with Human .beta.1A sodium channel subunit cDNA or occytes injected with Human .beta.1A sodium channel subunit mRNA and optionally a sodium channel subunit mRNA. Human .beta.1A sodium channel subunit activity is measured by biological characteristics of the host cells expressing Human .beta.1A sodium channel subunit DNA. In the case of recombinant host cells expressing Human .beta.1A sodium channel subunit patch voltage clamp techniques can be used to measure channel activity and quantify modification of a sodium channel subunit ion flux as a function of Human .beta.1A sodium channel subunit protein. In the case of

oocytes patch clamp as well as **two-electrode voltage** clamp techniques can be used to measure sodium channel activity and quantify Human beta.1A sodium channel subunit protein. (Emphasis added).

See also the abstract and the specific steps of the method in the Examples starting at col. 29, Example 1. (All emphasis added).

## Response to Arguments

Applicants acknowledge that that the specification of Qin et al. actually disclose a method of screening for a modulator (compound) of sodium channel activity comprising the steps of co-expressing a protein closely related to a human  $\beta 1A$  sodium channel subunit protein and a sodium channel  $\alpha$  subunit protein wherein the recombinant cell elicits a sodium ion flux. But argue that the present invention requires that the substrate is comprised of a first surface part and an opposite second surface part, wherein the first part has a plurality of sites each of which is adapted to hold an ion channel-containing structure. Thus, Qin et al fail to disclose all the elements in the method steps of the presently claimed invention. That is, it appears that Qin et al require co-expression of sodium channel subunit proteins and screening for compounds that either increase or decrease the capacity to open the sodium channel, whereas

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Applicants' claims require only a single expression vector in a method of identifying proteins which cause an electrophysiological change in a cell. Additionally, claim 1 of the present invention is not screening for a compound that effects the sodium channel as disclosed by Qin et al.

In reply, attention is again directed to Qin's disclosure cited above:

Particularly preferred cell based assays (or cell membrane assays, if suitable) are those where the cell expresses an endogenous or recombinant sodium alpha. channel subunit simultaneously with recombinant human .beta.1A. In these assays, a putative modulating compound can be analyzed for its effect on electrophysiological changes to the sodium flux upon the cell for altered expression of beta1A expression, or altered expression of the alpha/beta1A complex. Cells expressing recombinant human beta 1A are subjected to electrophysiological analysis to measure the total influx of sodium ions across the cell membrane by way of voltage differential using techniques well known by artisans in the field and described herein, including patch clamp voltage techniques ....

Furthermore, applicants in their previous REMARKS acknowledged that Qin describes cells being transfected with cDNA or mRNA molecules encoding a sodium gated/31A subunit and the subsequent measurement of biological activity using electrophysiological techniques including in response to a test agent.

Given the broadest reasonable interpretation of the claim and absent adequate description of the claimed and argued "the substrate is comprised of a first surface part and an opposite second surface part" is fully met by Qin's disclosure of patch membrane (substrate) two parts, as cited above. Applicants' arguments as to the requirement of a single vector are not commensurate in scope with the claims which do not recite any vector.

Claims 1-2, 7-13 and 15, as amended and added, are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Maher (6969449).

Maher discloses at e.g., col. 12, line 30 up to the Examples, particularly Example 10:

- Instrumentation including electrodes, and electrode arrays for reliably generating uniform electrical fields in cultures of living cells in aqueous solution.
- Multiwell plates comprising surface electrodes for high throughput and miniaturized stimulation and analysis of ion channel or cellular activities.
- Systems for high throughput analysis of ion channel and cellular activities and for use in drug discovery, analysis, screening and profiling.
- Methods for modulating the transmembrane potential of a living cell via the use of repetitive electrical stimulation.
- 5) Methods for screening the effects of test compounds on the activities of voltage regulated, and non-voltage regulated ion channels, transporters and leak currents.

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Including determining state-dependent pharmacological activity of compounds against ion channel and transporter proteins.

- 6) Methods for profiling and selecting cells or clones based on their response to electrical stimulation.
- 7) Methods for quantitative determination of cellular and ion channel parameters in a high-throughput manner, and for quantification of the pharmacological effects of compounds on those parameters.
- 8) Methods for the introduction of exogenous compounds into the intracellular spaces of cells.
  - 9) Methods for modulating the transmembrane potential of intracellular organelles, and for screening test compounds against ion channels in these organelles.
  - 10) Methods for characterizing the physiological effect of the transmembrane potential on the function and regulation of physiological and biochemical responses, including gene expression, enzyme function, protein activity and ligand binding.
  - 11) Methods for programming or training adaptive neuronal networks or bio-computers for specific functional or logical responses.
- 12) Methods for providing efficient neuronal interfaces for prosthetic devices implanted into an animal, including a human.

The invention also provides non-human animals expressing one or more hybrid olfactory receptor sequences of the invention, particularly human olfactory receptor sequences. Such expression can be used to determine whether a test compound specifically binds to a mammalian olfactory transmembrane receptor polypeptide in vivo by contacting a non-human animal stably or transiently infected with a nucleic acid derived from the library of the invention with a test compound and determining whether the animal reacts to the test compound by specifically binding to the receptor polypeptide.

## Response to Arguments

Applicants state that Maher et al. (similar to Qin et al.) discloses a method of screening for a modulator (compound) of sodium channel activity comprising the steps of selecting cells or clones based on their response to electrical stimulation. Thus, Maher et al. also fail to disclose all the elements in the method steps of the presently claimed invention. That is, it appears that Maher et al. require external electrical stimulation for selection of cells or clones, and for the screening methods that measure the effects of test compounds on regulated ion channels.

In reply, since applicants present the same arguments as in Qin above hence, the reply is incorporated herein. Applicants' arguments that Maher appears to require external electrical stimulation for selection of cells is not precluded from the

claims which require the determination of electrophysiology of the cells.

No claim is allowed.

#### Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

This application contains claims 3, 10, 12 and 14 drawn to non-elected invention. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (571) 272-0812. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571 273-8300. Information regarding the status of an application may be obtained from the Patent Application Information

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/TERESA WESSENDORF/

Primary Examiner, Art Unit 1639

Application Number

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